



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,937	04/08/2004	Lisa Lynn Shafer	P-21023.00US	9727
27581	7590	08/30/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			REIDEL, JESSICA L	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TAL

Office Action Summary	Application No. 10/820,937	Applicant(s) SHAFFER, LISA LYNN	
	Examiner Jessica L. Reidel	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-69 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 6 is objected to because of the following informalities: "the sympathetic nerve is the splenic nerve" appears to be a typographical error because Claim 1 only discloses the limitation of "the sympathetic neuron". The Examiner suggests changing the Claim to recite, "the sympathetic neuron is one of the splenic nerve". Appropriate correction is required.
2. Claim 26 is objected to because of the following informalities: "vagusnerve" appears to be a typographical error. The Examiner suggests changing the Claim to recite, "vagus nerve". Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 14-24, 26-30 and 33-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tracey (U.S. 6,610,713) in view of Rezai (U.S. 2002/0116030). As to Claims 1, 14, 26, 27 and 33 Tracey discloses a method for inhibiting the release of a pro-inflammatory cytokine from a mammalian cell comprising stimulating a neuron (i.e. the vagus nerve) of a mammalian subject in an amount effective to inhibit the release of the pro-inflammatory cytokine (see Tracey column 10, lines 17-56). Tracey differs from Claims 1, 14, 26, 27 and 33

Art Unit: 3762

in that the neuron stimulated is one of the parasympathetic nervous system rather the sympathetic nervous system.

Rezai, however, discloses a method of stimulating a neuron of the sympathetic nervous system in order to affect neurotransmission in order to treat a variety of physiological disorders associated with the sympathetic nervous system such as cardiac, vascular and renal diseases (see Rezai Abstract, page 1 paragraphs 4 and 5, page 3 paragraph 30 and page 6 paragraph 47). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Tracey in view of Rezai to stimulate a neuron of the sympathetic nervous system to treat a variety of physiological disorders associated with the entire autonomic nervous system.

5. As to Claim 2 and 28, the previously modified Tracey reference discloses that the stimulating comprises applying an electrical pulse to the neuron (see Rezai page 2, paragraph 19).

6. As to Claims 3 and 4, the previously modified Tracey reference discloses that the electrical pulse is applied via a pulse generator, which may be implanted on, or adjacent to, the electrode or at a remote site (see Rezai page 4, paragraph 37).

7. As to Claim 5, the previously modified Tracey reference discloses that a plurality of electrical pulses is applied to the neuron (see Rezai page 5, paragraph 38). The Examiner takes the position that the oscillating electrical signal capable of being applied continuously or intermittently and having a specified pulse width is synonymous with a plurality of electrical pulses being applied to the neuron.

8. As to Claims 15-17, see Tracey column 1, lines 28-34 and column 3, lines 6-18.

Art Unit: 3762

9. As to Claim 18, the Examiner takes the position that since Tracey discloses a method for inhibiting the release of a pro-inflammatory cytokine such as IL-8 (see column 6, lines 65-61). It is inherent that Tracey includes a chemokine since a chemokine is synonymous with various cytokines produced in acute and chronic inflammation that mobilize and activate white blood cells such as IL-8.

10. As to Claims 19-22 and 34-35, see Tracey column 1, lines 46-67, column 2, lines 1-34, column 3, lines 18-67, column 4, lines 1-67 and column 5, lines 1-5.

11. As to Claims 23-24 and 29-30, the previously modified Tracey reference discloses that a ganglion is stimulated and that a postganglionic neuron is stimulated (see Tracey column 4, lines 5-8).

12. As to Claims 36-69, the Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made since each disease is an inflammatory disease and thus within the general field of the previously modified Tracey reference. One would expect the method of the modified Tracey reference to work on any inflammatory disease.

13. Claims 6-13, 25, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tracey in view of Rezai and Gross et al. (U.S. 2003/0045909) (herein Gross). The previously modified Tracey reference differs from Claims 6-13, 25, and 31-32 in that the stimulation applied to the sympathetic nerve is not the splenic nerve.

Gross, however, discloses an apparatus and method for treating patients by application of electrical signals to a selected nerve or nerve bundle (see Gross page 1, paragraph 4), such as one or more sympathetic nerves that affect the behavior of a spleen (see Gross page 12, paragraph

Art Unit: 3762

233, page 19, Claim 164 and page 20, Claim 175). The Examiner takes the position that “an autonomic nerve” and “one or more sympathetic nerves that affects the behavior of a spleen” encompasses the splenic nerve. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Tracey in view of Rezai and Gross to stimulate one or more sympathetic nerves that affects the behavior of a spleen such as the splenic nerve in order to treat a condition of the spleen.

14. As to Claims 9 and 10, the previously modified Tracey reference discloses that the stimulating comprises applying an electrical pulse to the neuron (see Rezai page 2, paragraph 19).

15. As to Claims 11 and 12, the previously modified Tracey reference discloses that the electrical pulse is applied via a pulse generator, which may be implanted on, or adjacent to, the electrode or at a remote site (see Rezai page 4, paragraph 37).

16. As to Claim 13, the previously modified Tracey reference discloses that a plurality of electrical pulses is applied to the neuron (see Rezai page 5, paragraph 38). The Examiner takes the position that the oscillating electrical signal capable of being applied continuously or intermittently and having a specified pulse width is synonymous with a plurality of electrical pulses being applied to the neuron.

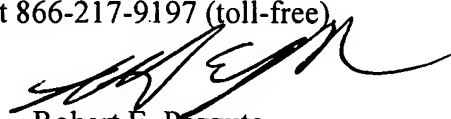
Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3762

Jessica L. Reidel